Automating Document Control Processes to Comply with FDA and ISO Requirements:

Increase Efficiency, Ensure Compliance and Improve Profitability
Document control systems exist to ensure that manufacturers build products that are safe and reliable. ISO and FDA Current Good Manufacturing Practices (CGMP) presume that both the process and documentation that directs company processes follows pre-approved methods, and that any change to these methods is restricted to authorized personnel and tracked for future review. ISO standards and FDA regulations mandate that all companies that manufacture regulated products have a document change control system.

Inefficient document control systems slow the time it takes to get a regulated product to market, which subsequently causes manufacturers to lose millions of dollars of potential profits. This significant revenue loss can primarily be attributed to the inefficiencies that occur when using a paper/hybrid-electronic system. (Wherein document change control is managed in a manual fashion or using a combination of both paper and electronic files.) Manual systems are error-prone, cause delays, and introduce product quality problems that can result in stringent regulatory penalties. In fact, the FDA cites inadequate change management as a major cause for “Form 483” observations. Examples of common shortcomings include documents with missing dates or missing numbering schemes, uncontrolled copies and document changes without approvals or explanations. To eliminate these inadequacies, regulated companies are turning to electronic quality management systems to automate document control.

Today’s quality management systems provide integrated solutions to handle everything from corrective and preventive actions (CAPA) to change control and training. This white paper concentrates on document control processes within the quality system lifecycle, and provides insight into the capabilities needed to automate change control processes that will increase efficiency, ensure compliance with FDA requirements and improve overall profitability.

**Overview**

To eliminate the problems regulated companies are being cited for during inspections and audits, a change management / change control software solution must incorporate the following capabilities:

- Compliance Management
- Document Management
- Revision Control
- Intuitive System Administration Tools
- General User / Viewer Usability
- Open Architecture
- Complete Implementation and Validation Tools
Compliance Management

In order to move from a manual, paper-based system to an electronic, automated system, manufacturers must follow the guidelines outlined in regulation 21 CFR Part 11 for using electronic records and signatures. These guidelines include the following:

- **Multi-password access and signature...forced expiration** - The FDA requires two distinct identification components for compliant document change control: one for login and one for document approval. Options should be available for configuring the length of the password and alphanumeric combinations to maintain the highest level of security for the system. Password expiration, encryption and certification are also necessary.

- **Account and intruder lockout** - An account should automatically be locked for both login and approval any time a password or login is compromised. If any unauthorized attempt is made during either login or approval, the intruder lockout feature is activated (after a certain number of unauthorized login attempts or approval attempts has been reached). The system administrator should be able to customize the number of password attempts.

- **Signature manifestation on the document** - Signature manifestations are required for FDA-regulated companies to meet Part 11 requirements and should automatically be appended to each document. Manifestations should include first name, last name, date, time and meaning of the electronic signature. Manifestations should also appear on all human-readable forms that are either viewed electronically or printed on paper.

Figure 1 – Change control as part of the quality management lifecycle
• **Change control rationale** - Changes made to document metadata should be tracked. (Metadata contains document attributes like title, author, etc.) Each time a change is made to any metadata, a user must enter a reason for the change. The system must track each of these changes and make them available for review.

**Document Management**

Document management capabilities boost efficiency and ensure compliance by eliminating labor-intensive tasks such as the physical routing of documents for approval, storage and distribution.

• **Format agnostic** - The system must be able to control any document (e.g., Microsoft Word® documents, Excel® spreadsheets, CAD, video, audio, etc.) regardless of the application used to create it.

• **Document lifecycle management** - Documents must be managed through their lifecycle statuses of Draft, Released and Archived. (See Figure 2.) Lifecycles can be based on document type and need to automatically adjust document security based on lifecycle status.

• **Audit trail history / record archiving** - A secure, time-stamped audit trail of all changes made to any record should be maintained and accessible to the appropriate users and departments. All of this information needs to be automatically captured and secured. Reporting functionality should track past versions, metadata and approval history of the record, from the time it was created until the present.

• **Centralized, secure repository** - Documents should be securely stored to ensure only authorized access and protection against disaster.

• **Document cross-linking** - In manufacturing environments, documents complement one another. For example, a form may be associated to a standard operating procedure (SOP), or an equipment manual associated with a maintenance drawing, etc. A document control system should allow document linking to provide users the relevant information needed to do their jobs.

**Revision Control**

Document revision control represents one of the most time-consuming tasks, and one that is most ripe for automation. When automating document control processes, users will find that with the right solution they can accomplish the following:

• **Ensure control of all document versions/revisions** - Be able to present the currently released document, while simultaneously managing collaborative changes that will result in a new revision.
• **Control rogue documents** - A system should alleviate the consequences of uncontrolled electronic documents by enabling copies to “self destruct” after the configurable time allotted to the document expires. For example, a document that is saved outside the system and emailed to another person would be impossible to open 48 hours after it is copied from the system. Similarly, a system should offer capabilities to manage printed documents. Any time a document is printed from the system, expiration dates and times should be automatically watermarked prominently on the document.

• **Automate document routing, approval and escalations** - Document routing and approvals should be automated to notify all approvers or collaborators in the authorization chain. Configurable, time-based escalation features can expedite approval and collaboration cycles in case users are delayed or unavailable. Upon approval, old versions should automatically revision, while users affected by the change are assigned a task to be trained or re-trained. (Training is addressed in a supplementary white paper available from MasterControl.)

• **Automatic document replacement (draft to release to archive)** - As documents are approved, old versions should automatically move to an archive vault and be replaced by the newest version. This eliminates any possibility of employees using the incorrect version. (See Figure 2.)

• **Unlimited pre-determined and ad-hoc routing steps** - Routes for document collaboration or approval should be pre-configurable for use at any time or have the option to be added on the fly. Each step in a route can have one or many approvers assigned to it to allow for the creation of a combination of serial and parallel routing.

• **Real-time, repeatable email notification** - Customizable email notifications should be provided to alert users in a route to take action on their specific tasks. Managers would be notified when tasks are completed to proactively monitor collaboration, change management, approval and training cycles.
• **Electronic signature/approval history tracking** - Managers should be able to view electronic signature details, approval history and cycle statuses as needed during the change management process.

• **Automatic distribution upon approval** - After the completion of approval cycles, documents should be automatically distributed to users affected by the change and old versions should be archived. (See Figure 2.)

**Intuitive System Administration Tools**

Easy-to-use system administration tools should be provided to comfortably manage the entire system:

• **User-friendly route builder capabilities with drag-and-drop visual interface** - System administrators should be able to easily build approval routes, thereby reducing the need for dedicated IT resources.

• **Configurable user rights and roles** - The system should provide built-in tools that enable system administrators to easily create a variety of individually tailored user and security roles. For example, some users may only need limited “find and view” rights while others may need broad edit privileges. Managing these roles when adding users and passwords for login or electronic signatures within a centralized location improves usability and saves time.

• **Automated conversion/publishing to PDF** - Optional document publishing to PDF throughout the document lifecycle should be completely automated. PDF conversion from multiple document types into a common, unalterable format improves efficiency and reduces costs by eliminating additional desktop software that would be required for users to view documents.
• **Advanced system reporting** - A variety of standard and custom reports like audit trail, master list, cycle time and revision history should be available to help system administrators proactively manage the system and provide peace of mind with audit and inspection preparedness.

**General User / Viewer Usability**

A change control management system should provide users an intuitive interface to increase usability and system acceptance:

• **Browser-based / thin client access** - A browser-based system provides industry standard connectivity, ease-of-use and company-wide access regardless of physical location. This helps connect remote employees, customers and supply chain members to the change management loop. These members can participate in processes like collaboration, document change, notification and training from any location.

• **Full-text / metadata searching** - Capabilities to search either the metadata or the full text of all documents using any keyword or string of words should be available. Search results should provide only a list of documents that both meet the search criteria and match user security rights. Boolean and wildcard search operators should be provided to narrow down search results.

• **Finding documents through graphically linked groupings** - The system should offer users a helpful graphical interface that allows them to quickly find the information required to do their jobs. Similar to a Windows® or Macintosh® desktop tree, users should be able to point and click on folders that contain additional folders, projects and individual documents like work instructions, procedures, etc. Documents must be able to reside in multiple trees to facilitate the search logic of different users and should automatically update upon revision to ensure that the most current document is always used.

**Open Architecture**

A change control system should provide system administrators a platform that is industry-proven and easy to deploy. Users need a familiar and intuitive interface to enhance usability and system acceptance.

• **Web-based** - Cloud-based systems provide users and IT managers alike with a powerful, industry standard platform that is easy to use and offers access to authorized users. With Web-based solutions, companies can leverage industry-standard SSL and 128-bit encryption capabilities to secure the data communications that take place between the Web browser and the application, while still maintaining the benefits of 24x7, anytime-anywhere access for authenticated users.
• **Integration with other applications** - Open system architectures, platforms and industry-common SQL database technologies provide flexible integration gateways to other quality system applications like CAPA, training, etc. (See Figure 1.) Integrating quality subsystems to work in tandem helps organizations leverage all the necessary data and information to enable decision making that enhances product quality, ensures compliance and increases profits. Large corporate systems like MRP software can also be integrated to share information and data affected by changes in procedures, drawings, bills of lading, etc.

• **Easy-to-use graphical user interface (GUI)** - An intuitive interface throughout the application allows system administrators to easily build “visual” routes and manage the system for collaboration and change management approval cycles. And, end users can quickly find the information they need. An easy-to-use GUI is an important ingredient for a successful implementation because it improves overall system use and acceptance.

**Complete Implementation and Validation Tools**

FDA-regulated companies looking for document control, change management or change control systems should search out applications that have complete services for implementation and validation.

• **Training for IT managers, system administrators and general users** - A variety of training should be available for system administrators, advanced users (Power Users) and general users (Viewers) that is mindful of the product, the industry and the customer’s unique practices. Such training should be available at the vendor’s facility, at the customer site, live over the Web, and/or pre-recorded.

• **Validation tools and services** - Organizations should ensure the solution provider has been audited by similar companies within the appropriate industry and have a good user-base of references. Vendors should provide all the necessary validation tools and services for buyers to either perform their own validation or elicit complete services from the vendor. The vendor’s validation tools and services should follow Good Automated Manufacturing Practice (GAMP) guidelines for computer systems validation. Vendors that offer their own validation tools and services are more familiar with the system and can usually accelerate validation.

**Conclusion**

FDA-regulated companies would agree that moving from a manual, paper environment to an electronic system for document control and change management is challenging. It is an endeavor that includes costs for user training, IT infrastructure upgrades (if necessary) and system validation. However, most (if not all) of the companies that have made the transition can prove that the benefits
of automation include a faster return on investment (ROI). More importantly, the automation of these change control tasks eliminates common errors that are cited in FDA 483 observations yielded by companies that still use manual, paper-based/hybrid-electronic systems.

**About MasterControl**

MasterControl Inc. creates software solutions that enable life science and other regulated companies to deliver life-improving products to more people sooner. MasterControl’s integrated solutions accelerate ROI and increase efficiencies by automating and securely managing critical business processes throughout the entire product lifecycle. More than 1,000 companies worldwide, ranging in size from five employees to tens of thousands, rely on MasterControl cloud solutions to automate processes for new product development, clinical, regulatory, quality management, supplier management, manufacturing and postmarket surveillance. MasterControl solutions are well-known for being scalable, easy to implement, easy to validate and easy to use. For more information, visit [www.mastercontrol.com](http://www.mastercontrol.com).

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